

27294. Concentrated extract of alfalfa. (F.D.C. No. 44666. S. No. 41-445 R.)

QUANTITY: 8 cases, 24 8-oz. btls. each; 6 cases, 13 16-oz. btls. each; and 9 cases, 12 32-oz. btls. each, at San Francisco, Calif.

SHIPPED: 6-8-59 and 1-8-60, from American Fork, Utah, by Lucerne Laboratories of Utah.

LABEL IN PART: (Btl.) "Lucerne Concentrated extract of alfalfa (Medicago Sativa) it is a dietary supplement * * * Lucerne Is Not A Medicine One teaspoonful (5 Mls) contains: * * * 0.00586 Mg. Iron Three glasses daily furnish: * * * 0.02 mg. 12% of min. Daily Reqt. * * * Also micro-amounts of the many other elements present (and combined naturally) in the Lucerne,—the oldest known plant—from which made; for which elements no official standard of requirement has been established. Many of these elements may be deficient in foods of every day variety. * * * All materials used in the manufacture of Lucerne are of USP XIII, National Formulary VIII, or of CP (Reagent) quality and are so guaranteed * * * Lucerne Laboratories of Utah * * * American Fork, Utah."

ACCOMPANYING LABELING: Leaflet entitled "Lucerne * * * Alfalfa Nature's Rarest Gift to Man and Animal."

LIBELED: 6-17-60, N. Dist. Calif.

CHARGE: 403(a)—when shipped, the labeling statement "One teaspoonful (5 Mls) contains: * * * Iron * * * Three glasses daily furnish * * * 12% of Min. Daily Reqt." was false and misleading since it was contrary to fact; and the labeling statements "Also micro-amounts of the many other elements present" and "unexcelled content of basic and trace minerals," and the listing of the trace elements in the labeling were false and misleading since such elements and trace minerals were present in insignificant amounts for special dietary food purposes; the label statements "Lucerne contains * * * sucrose, which (in the process) is converted to Delta-glucose and Fructose, forms most assimilable by the human system," and "Lucerne contains * * * sucrose," and "The sugar contained in Lucerne * * * more assimilable," were false and misleading since sucrose is as readily assimilable by the normal individual as glucose and fructose; and the labeling statement "All materials used in the manufacture of Lucerne are of USP XIII and National Formulary VIII, or of CP (Reagent) quality," was false and misleading since the alfalfa in the article was not of such quality and since USP XIII and National Formulary VIII are not effective as standards of quality; 403(i) (2)—the article was fabricated from two or more ingredients and its label failed to bear the common or usual name of each such ingredient, since the ingredients of the unknown solution of the article were not declared on the label; and 403(j)—the article purported to be and was represented as a food for special dietary uses by reason of its vitamin and mineral content, and its label failed to bear, as required by regulations, a statement of the proportion of the minimum daily requirement for vitamins A, B, and D, supplied by the article when consumed in a specified quantity during a period of one day; and it also failed to bear the statement "The need for manganese, sulfur, barium, chromium, fluorine, molybdenum, strontium, vanadium, lithium, beryllium, cobalt, rubidium, tin, zinc, aluminum, silica, boron, lead, silver, and titanium, in human nutrition has not been established."

The libel also alleged that the article was misbranded under the provisions of the law relating to drugs as reported in notices of judgment on drugs and devices, No. 6393.

DISPOSITION: 8-29-60. Consent—claimed by Lucerne Laboratories of Utah, and released for relabeling.

27295. Kelp-Ette tablets. (F.D.C. No. 43959. S. No. 79-796 P.)

QUANTITY: 24 500-tablet btl., 24 1,000-tablet btl., and 24 2,000-tablet btl. at Hobart, Ind., in possession of Nelson's Natural Foods.

SHIPPED: Powdered kelp was shipped on 11-19-57, from Outer Harbor, San Pedro, Calif.

LABEL IN PART: (Btl.) "5-Grain Tablets * * * Nelson's Kelp-Ettes * * * A Pure Vegetable Sea Food Containing an abundance of Safe Natural Iodine Plus Other Minerals, Trace Elements, Organic Compounds and Vitamins Pressed from Pure Ocean Kelp. * * * Packed and Distributed by Nelson's Natural Foods * * * Battle Creek, Michigan * * * Nelson's Kelp-Ettes also contain Traces of the following Vitamins: Choline-Niacin-Carotene-Riboflavin Plus the following Organic Compounds: Alginic Acid-Chlorophyll-Lecithin-Manitol * * * 18 tablets * * * contain in milligrams * * * iron 5.8 * * * also undeterminable small amounts of Trace Elements of: Aluminum, Barium, Boron, Chromium, Lithium, Nickel, Silicon, Silver, Strontium, Titanium, Vanadium and Zinc."

ACCOMPANYING LABELING: Leaflets entitled "More Buoyant Health" and loose bottle labels for all size bottles.

RESULTS OF INVESTIGATION: The Kelp-Ette tablets were manufactured by the dealer from powdered kelp which had been shipped as described above. Examination showed that the tablets contained approximately 50 percent of the declared amount of iron.

LIBELED: 12-14-59, N. Dist. Ind.

CHARGE: 402(b)(1)—while held for sale, a valuable constituent, iron, had been omitted from the article; 403(a)—the statement in the labeling of the article that each 18 tablets contained 5.8 milligrams of iron was false and misleading; 403(a)—the labeling also contained false and misleading representations that the article, as compared to generally available foods, was superior in its content of minerals, trace elements, organic compounds, and vitamins; that the food supplies generally available were nutritionally deficient and inferior and that they lack sufficient quantities of the minerals, including trace minerals, contained in the article; that the trace elements in the article were needed in human nutrition to build and maintain the body; that the article was superior, as compared to foods generally available, in view of its content of choline, potassium, sodium, sulfur, magnesium, manganese, copper, trace elements, chlorine, carotene, riboflavin, niacin, alginic acid, chlorophyll, lecithin, and manitol; 403(a)—the statement in the labeling, "Your body, you know, is formed of mineral elements," was false and misleading since it was contrary to fact; and 403(j)—the article purported to be and was represented as a food for special dietary uses by reason of its vitamin and mineral content and its label failed to bear, as prescribed by regulations, a statement of the minimum daily requirement for niacin, vitamin A and riboflavin supplied by such food when consumed in a specified quantity during a period of one day; and the label also failed to bear the statement "The need for choline, sulfur, manganese, aluminum, barium, boron, chromium, lithium, nickel, silicon, silver, strontium, titanium, vanadium, and zinc in human nutrition has not been established," and a statement of the